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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/240,455 01/29/99 MUNDSCHEK

D 15050.5

EXAMINER

HM12/0329

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ART UNIT

PAPER NUMBER

1615

DATE MAILED:

03/29/00

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/240,455

Applicant(s)

Mundshenk

Examiner

Todd D. Ware

Group Art Unit
1615



☒ Responsive to communication(s) filed on Jul 6, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-10 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1615

DETAILED ACTION

Receipt of disclosure statement filed 7-6-99 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 claims aerosol and non-aerosol delivery devices whereas the claim it depends from (claim 7) claims only aerosol dispensers. This is apparently a typographical error, since the aerosol of claim 7 can not be non-aerosol in claim 8. Correction is requested.

It is unclear what the combination of claim 10 is. Claim 10 claims the composition of claim 9 wherein the composition is in contact with the roof of the mouth. It appears that this is one composition and does not include at least one other composition in the formulation to render the formulation to be a combination of at least two compositions.

Art Unit: 1615

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundshenk et al (WO 97/43407; hereafter '407 in combination with Heiber et al (US 5,766,620; hereafter '620).

'407 teaches a method of preparing inactivated toxins and bioactive peptides and methods for their administration involving inactivation of a toxin or bioactive peptide with ozone and administering the inactivated peptide parenterally as a vaccination.

'620 is relied upon for teaching that peptides are buccally administrable.

'620 employs adhesive tablets containing a peptide and a permeation enhancer to deliver the peptides buccally.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '407 and '620 to provide a non-invasive route of administration for inactivated peptides to vaccinate an individual.

Art Unit: 1615

5. Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundshenk et al (WO 97/43407; hereafter '407 in combination with Kamiya et al (US 4,948,588; hereafter '588).

'407 teaches a method of preparing inactivated toxins and bioactive peptides and methods for their administration involving inactivation of a toxin or bioactive peptide with ozone and administering the inactivated peptide parenterally as a vaccination.

'588 is relied upon for teaching buccal administration of peptides by spraying compositions of peptides with absorption enhancing agents in aerosol and non-aerosol formulations.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '407, ^{and} '588, and ~~'567~~ to provide a non-invasive route of administration for inactivated peptides to vaccinate an individual.

6. Claims 1- 4, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundshenk et al (WO 97/43407; hereafter '407 in combination with Heiber et al (US 5,766,620; hereafter '620) and further in combination with Cardinaux et al (US 5,578,567; hereafter '567).

'407 teaches a method of preparing inactivated toxins and bioactive peptides and methods for their administration involving inactivation of a toxin or bioactive peptide with ozone and administering the inactivated peptide parenterally as a vaccination.

'620 is relied upon for teaching that peptides are buccally administrable.

Art Unit: 1615

'620 employs adhesive tablets containing a peptide and a permeation enhancer to deliver the peptides buccally.

'567 is relied upon for teaching mucosal peptide formulations that contain benzalkonium chloride as a preservative.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '407 and '620 to provide a non-invasive route of administration for inactivated peptides to vaccinate an individual that contains benzalkonium chloride to protect the composition against bacterial contamination.

7. Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundshenk et al (WO 97/43407; hereafter '407 in combination with Kamiya et al (US 4,948,588; hereafter '588)and further in combination with Cardinaux et al (US 5,578,567; hereafter '567).

'407 teaches a method of preparing inactivated toxins and bioactive peptides and methods for their administration involving inactivation of a toxin or bioactive peptide with ozone and administering the inactivated peptide parenterally as a vaccination.

'588 is relied upon for teaching buccal administration of peptides by spraying compositions of peptides with absorption enhancing agents in aerosol and non-aerosol. '567 is relied upon for teaching mucosal peptide formulations that contain benzalkonium chloride as a preservative.

Art Unit: 1615

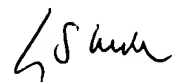
Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '407 and '588 to provide a non-invasive route of administration for inactivated peptides to vaccinate an individual that contains benzalkonium chloride to protect the composition against bacterial contamination..

Conclusion

8. Currently, no claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.



Gollamudi S. Kishore, PhD
Primary Examiner
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3-24-00